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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,319	04/22/2005	Ellen J Baron	222310-US	9127

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EXAMINER	
JOHANNSEN, DIANA B	

ART UNIT	PAPER NUMBER
1634	

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05/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,319	BARON ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2007 and 25 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5 and 6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 October 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This action is responsive to the Response filed October 25, 2007 and the complying complete set of claims filed January 25, 2008. Claims 1-3 and 5-6 have been amended, and claims 4 and 7-8 have been canceled. Claims 1-3 and 5-6 are now pending and under consideration. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and/or objections not reiterated in this action have been withdrawn. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

3. It is again noted that certified copies of foreign priority applications EP 02027272.0 and EP 03007458.7 have not been received in the instant application. Although applicant has provided a copy of an acknowledgement postcard and other evidence indicating that the documents were provided in corresponding PCT application PCT/US03/38783 on February 26, 2004, the instant application (which is a later filed 371 of that PCT application) does not include the documents, and the Form PCT/DO/EP/903 mailed to applicant on August 23, 2006 does not indicate receipt of the priority documents in the instant application.

Information Disclosure Statement

4. The information disclosure statement filed October 25, 2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the citations for both US

Patent documents are incomplete, and because the complete copies of the Humar et al and Reid et al references noted in applicant's response of October 25, 2007 have not been received. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

5. It is also noted that applicant may wish to provide a new 1449 including a citation for the Pelloux et al abstract/reference discussed at pages 4-5 of the reply of October 25, 2007.

Claim Rejections - 35 USC § 102

6. In view of the amendment of independent claim 1 to require the limitation "wherein said step of quantifying the amount of said nucleic acid is performed by means of amplification which is monitored in real time by means of a hybridization probe, further comprising the step of monitoring temperature dependence of hybridization," the prior rejection of claims 1-2 as being anticipated by Angen et al is withdrawn. Applicants' arguments with regard to the rejection are moot in view of the withdrawal of the rejection.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. The following are new grounds of rejection necessitated by applicants' amendments:

9. Claims 1-3 and 5-6 rejected under 35 U.S.C. 102(e) as being anticipated by Cockerill et al (US 7,074,598 B2 [11 July 2006; filed 25 September 2002]).

Cockerill et al disclose methods of detecting vancomycin-resistant *enterococci* in biological samples, which methods employ real time PCR (see entire reference, particularly, e.g., col 1, line 27-col 2, line 14; col 5, lines 3-34; and col 11, line 34-col 14, line 55). Cockerill et al disclose the analysis by their methods of samples including "anal or peri-rectal swabs, stool samples, blood, and body fluids" (see col 2, lines 66-67). Further, in detecting and determining the type of vancomycin-resistant enterococci present in such samples, Cockerill et al achieve the objective of "analyzing the presence of a bacterial pathogen in a clinical sample," as set forth in the preamble of independent claim 1. Cockerill et al disclose the analysis of both samples and nucleic acids extracted therefrom, including total RNA or DNA extracted from clinical samples (see, e.g., col 9, lines 16-30), and therefore disclose "at least partially isolating nucleic acid" as set forth in the first step of claim 1. Cockerill et al disclose real-time PCR that is monitored by analysis of hybridization probe melting temperatures, allowing the identity of the specific target sequences present to be both detected and quantitated (see, e.g.,

col 12, line 59-col 14, line 55); therefore, Cockerill et al teach a "quantifying" step meeting the requirements of the claims. Cockerill et al also exemplify the practice of their method (see, e.g., Example 3), and disclose that that samples with positive signals at melting temperatures corresponding to the various positive controls employed allow determination of the presence of the target sequence indicated by the corresponding positive control, while samples having melting curves that are "not above baseline" are considered negative (see, e.g. col 20, lines 27-40). Thus, Cockerill et al inherently disclose that positive signals must exceed a certain level (i.e., a type of cut off value) to be considered positive, and that signals below baseline are considered negative. With regard to claim 2, it is noted that Cockerill et al do not explicitly disclose multiple cut-off values; however, in any case in which a positive signal is detected (i.e., in which the presence of vancomycin-resistant enterococci is detected by the method of Cockerill et al), one will have also inherently determined "whether said amount of nucleic acid....is less than a second predetermined cut off value which is less than said first predetermined cut off value," as required by claim 2. Specifically, such a result would indicate that the amount of nucleic acid presence is not less than such a value. Such a result meets the requirements of the claims, as the recitation of claim 2 does not require that any further manipulation or active step take place; rather, the "determining" of claims 1-2 merely indicate how data is to be interpreted based on the amount of nucleic acid that is determined to be present. With further regard to claims 3, 5, and 6, it is again noted that Cockerill et al disclose real time PCR, the analysis of blood, and the

analysis of *enterococci*, as set forth above. Accordingly, Cockerill et al anticipate the claimed invention.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634